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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,959	03/03/2004	Hal H. Katz	END-5011USNP	5088

27777 7590 12/27/2005  
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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/791,959

Applicant(s)

KATZ ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a system associated with medical procedures, classified in class 604, subclass 66.
- II. Claims 16-22, drawn to method of monitoring a patient, classified in class 604, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be used for a variety of surgical procedures and treatment options such as monitoring patient responses to drug induced states during brain surgery and/or procedures to which the patient is only locally medicated and not placed unconscious.

During a telephone conversation with Verne Kreger on 12/09/2005 a provisional election was made without traverse to prosecute the invention of Group II, claims 16-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

No information disclosure statement (IDS) was submitted and there is not in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is not considering any information disclosure statement.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 16, 17, 18, 20, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hickle et al. (US2003/0135087). Regarding claim 16, Hickle et al. discloses a micro-processor based system that uses at least one sensor to monitor physiological patient parameters and starts a patient record and also stores historical data (Figure 1, Page 2 [0011]).

Regarding claim 17, Hickle et al. further discloses a drug cassette system for delivering medication to the patient (Page 4, [0061]).

Regarding claim 18, Hickle et al. discloses the monitoring physiological conditions and disconnecting input signals and terminating a patient cases to start a new one (Page 17, [0162]).

Regarding claim 20, Hickle et al. discloses the step of querying the patient for consciousness (Figure 17).

Regarding claim 22, Hickle et al. discloses the step of priming an IV tube with a drug volume that is considered during the dose administration process (Page 14, [0135]).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C 103(a) as being unpatentable over Hickie et al. in view of Hickie (6,807,965). Hickie et al. meets the claim limitations as described above but does not include the step of delivering oxygen.

However, Hickie teaches a sedation device that dispenses oxygen. The reference teaches an apparatus that provides oxygen to the patient (Figure 7A).

At the time of the invention, it would be obvious to use method of Hickie et al. with apparatus of Hickie to dispense oxygen. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Additionally, Hickie provides the motivation that that oxygen is used as a delivery agent for sedation. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hickie stating the use of oxygen as a treating medium.

Claim 21 is rejected under 35 U.S.C 103(a) as being unpatentable over Hickie et al. in view of Hickie (6,807,965). Hickie et al. meets the claim limitations as described above but does not include the step of a patient activating a response device.

However, Hickie teaches a patient response device that can be used. The reference teaches an apparatus that allows user input (col 21, ln 8-14, and element 226)).

At the time of the invention, it would be obvious to use input device with Hickie et al. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Additionally, Hickie provides the motivation that the handheld device allows the patient to actively respond to the user. Therefore, one skilled in the

art would have combined the teachings in the references in light of the disclosure of Hickie stating the use of a handheld patient input device.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on Monday through Friday 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12/16/2011  
[Date]

  
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